

Marked- up copies of the foregoing amended claims are enclosed herewith.

REMARKS

The Official Action dated 18 June, 2002, has been carefully considered. In view of the foregoing amendments and these remarks, favourable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set in the June 18, 2002 Official Action. The initial due date for response, therefore, was September 18, 2002. A petition for a three (3) month extension of the response period is presented with this amendment and request for reconsideration, which is being filed within the three (3) month extension period.

The Official Action repeats and makes final the Restriction Requirement raised in the previous Official Action.

Furthermore, the previous rejection under 35 U.S.C. § 112, first paragraph, has been maintained. Consequently, claims 1-12, 16-17, 19 and 27-36 stand rejected as allegedly lacking adequate enablement.

Claims 4-7, 9, 27 and 30-32 stand rejected under 35 U.S.C. § 112 as allegedly being indefinite.

Claims 1-12, 16-17, 19 and 27-36 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not meeting the

written description requirement.

The above listed rejections constitute the entirety of the grounds set forth in the Official Action dated 18 June, 2002, for refusing allowance of this application. Each of these rejections is respectfully traversed for the reasons set forth below.

In accordance with the present amendments, the claims have been amended to specify a composition, rather than a cancer vaccine. Support for this amendment comes *inter alia* from the description at page 5, lines 16-27. The claims have been limited to fragments and derivatives of the amino acid sequence of Fig. 10, with claims to 791Tgp72 and methods for its isolation deleted. The terms "fragments" and "derivatives" have been further characterized. Support for this latter amendment comes *inter alia* from the claims as originally filed and from the description at page 14, lines 5-9. Accordingly, it is believed that the amendments to the claims introduce no new matter into the present specification. Entry of this amendment is, therefore, respectfully requested.

Turning attention to the Restriction Requirement, Applicants respectfully point out that the claims relating to Groups III and IV, as identified in the Official Action of October 2, 2001, have been deleted. This leaves only the question of whether it is proper to require restriction between Groups I and II.

Groups I and II, respectively, relate to the independent claims 1 and 13. Both of these claims were amended in response to the previous Official Action to call for fragments and derivatives of CD55 family polypeptides. They have been further amended presently to call for fragments and derivatives of the amino acid sequence of Fig. 10. The Examiner deems that restriction is appropriate on the basis that Durrant suggests the use of 791Tgp72 as an anti-cancer vaccine. While the correctness of this objection is not conceded, Applicant respectfully points out that claims 1 and 13 have the corresponding special technical feature of comprising, or encoding, fragments or derivatives of the amino acid sequence of 791Tgp72. Since the amino acid sequence of this antigen was unknown before the filing date of the instant application, such a special technical feature indeed defines a contribution over the prior art.

Applicants further respectfully refer the Examiner to the PCT Administrative instructions cited in the response to the previous Official Action. These clearly state that there is no lack of unity between a protein and the corresponding nucleic acid.

Reconsideration of the Restriction Requirement is therefore respectfully requested.

Turning attention now to the enablement rejection, Applicants respectfully point out that the claims have been amended to delete the term "cancer vaccine", and instead are directed to a "composition". Rejections based on the lack of

evidence that the claimed products lead to protection from cancer are therefore rendered moot.

Furthermore, the scope of the term "derivative" has been dramatically reduced to those having an amino acid sequence that differs from a fragment of Fig. 10 only by the substitution of 1 or 2 amino acids.

As pointed out in the response to the previous Official Action, the person skilled in the art would, at the priority and filing dates of the application, have been well able, without an undue need for experimentation, to identify fragments of the amino acid sequence of Fig. 10 that include a T cell epitope. Based on the knowledge of the characteristic residues of T cell epitopes, it would likewise be a matter of routine to make minor modifications to such fragments to arrive at the derivatives of the invention.

Indeed, the inventors have successfully applied algorithms that date from before the priority date of the application to the identification of T cell epitopes in the amino acid sequence of Fig. 10. Peptides based on the epitopes thus found are being produced for testing *in vivo* in mice.

Reconsideration and withdrawal of the enablement rejection is, therefore, respectfully requested.

In response to the rejection for alleged indefiniteness, the amino acid and nucleic acid sequences of Figs. 10 and 11 have been incorporated into the claims directly. This amendment therefore renders this ground of rejection moot.

As for the rejection based on alleged lack of written description, Applicants note that the Examiner's comments relate solely to the claimed derivatives. The present amendments now characterize such derivatives much more narrowly, as differing from fragments of the amino acid sequence only by the substitution of one or two amino acids. This is commensurate with the written description of the degree of identity between fragments of the amino acid sequence of Fig. 10 and the CDRs of the anti-idiotypic antibodies 105AD7 and 730, which appears at page 37, lines 16-28 of the present specification.

Applicants, therefore, respectfully request reconsideration and withdrawal of this rejection also.

Applicants believe that the present communication is fully responsive to the Official Action of June 18, 2002. In view of the foregoing amendments and remarks, it is respectfully submitted that all rejections have been overcome.

DANN DORFMAN HERRELL and
SKILLMAN, P.C.

Attorneys for Applicant

By Patrick J. Hagan
Patrick J. Hagan
Registration No. 27,643

PJH:ksk

MARKED-UP VERSION OF AMENDED CLAIMS

1. (Twice amended) A [cancer vaccine] composition comprising a fragment of a polypeptide of the CD55 family or a derivative thereof, wherein said fragment or derivative contains a T cell epitope, and wherein [the vaccine is capable of inducing an immune response in a patient, said immune response being a T cell response] said fragment is of at least seven contiguous amino acids from the following amino acid sequence:

Met Thr Val Ala Arg Pro Ser Val Pro Ala Ala Leu Pro Leu Leu Gly
1 5 10 15

Glu Leu Pro Arg Leu Leu Leu Leu Val Leu Leu Cys Leu Pro Ala Val
20 25 30

Trp Gly Asp Cys Gly Leu Pro Pro Asp Val Pro Asn Ala Gln Pro Ala
35 40 45

Leu Glu Gly Arg Thr Ser Phe Pro Glu Asp Thr Val Ile Thr Tyr Lys
50 55 60

Cys Glu Glu Ser Phe Val Lys Ile Pro Gly Glu Lys Asp Ser Val Ile
65 70 75 80

Cys Leu Lys Gly Ser Gln Trp Ser Asp Ile Glu Glu Phe Cys Asn Arg
85 90 95

Ser Cys Glu Val Pro Thr Arg Leu Asn Ser Ala Ser Leu Lys Gln Pro
100 105 110

Tyr Ile Thr Gln Asn Tyr Phe Pro Val Gly Thr Val Val Glu Tyr Glu
115 120 125

Cys Arg Pro Gly Tyr Arg Arg Glu Pro Ser Leu Ser Pro Lys Leu Thr
130 135 140

Cys Leu Gln Asn Leu Lys Trp Ser Thr Ala Val Glu Phe Cys Lys Lys
145 150 155 160

Lys Ser Cys Pro Asn Pro Gly Glu Ile Arg Asn Gly Gln Ile Asp Val
165 170 175

Pro Gly Gly Ile Leu Phe Gly Ala Thr Ile Ser Phe Ser Cys Asn Thr
180 185 190

Gly Tyr Lys Leu Phe Gly Ser Thr Ser Ser Phe Cys Leu Ile Ser Gly
195 200 205

Ser Ser Val Gln Trp Ser Asp Pro Leu Pro Glu Cys Arg Glu Ile Tyr
210 215 220

Cys Pro Ala Pro Pro Gln Ile Asp Asn Gly Ile Ile Gln Gly Glu Arg
225 230 235 240

Asp His Tyr Gly Tyr Arg Gln Ser Val Thr Tyr Ala Cys Asn Lys Gly
245 250 255

Phe Thr Met Ile Gly Glu His Ser Ile Tyr Cys Thr Val Asn Asn Asp
260 265 270

Glu Gly Glu Trp Ser Gly Pro Pro Pro Glu Cys Arg Gly Lys Ser Leu
275 280 285

Thr	Ser	Lys	Val	Pro	Pro	Thr	Val	Gln	Lys	Pro	Thr	Thr	Val	Asn	Val
290				295				300							

Pro	Thr	Thr	Glu	Val	Ser	Pro	Thr	Ser	Gln	Lys	Thr	Thr	Thr	Lys	Thr
305				310				315				320			

Thr	Thr	Pro	Asn	Ala	Gln	Ala	Thr	Arg	Ser	Thr	Pro	Val	Ser	Arg	Thr
				325				330				335			

Thr	Lys	His	Phe	His	Glu	Thr	Thr	Pro	Asn	Lys	Gly	Ser	Gly	Thr	Thr
340								345				350			

Ser	Gly	Thr	Thr	Arg	Leu	Leu	Ser	Gly	His	Thr	Cys	Phe	Thr	Leu	Thr
355								360				365			

Gly	Leu	Leu	Gly	Thr	Leu	Val	Thr	Met	Gly	Leu	Leu	Thr,			
370								375				380			

or wherein said derivative varies from said fragment only by the substitution of 1 or 2 amino acids.

5. (Thrice amended) A [cancer vaccine] composition according to claim 1 wherein the fragment or derivative includes part or all of the amino acid sequence consisting of amino acids 97-159 of [Fig. 10] the sequence shown in claim 1.

6. (Thrice amended) A [cancer vaccine] composition according to claim 5 wherein the fragment or derivative includes a sequence having at least five amino acids identical with corresponding amino acids of a contiguous stretch of seven

amino acids contained within amino acids 121-128 or 151-158 of [Fig. 10] the sequence shown in claim 1.

7. (Thrice amended) A [cancer vaccine] composition according to claim 1 wherein the fragment or derivative includes a sequence having at least six amino acids identical with corresponding amino acids of a contiguous stretch of nine amino acids contained within amino acids 83-93 of [Fig. 10] the sequence shown in claim 1.
11. (Amended) A [cancer vaccine] composition according to claim [10] 1 wherein the fragment is of at least nine contiguous amino acids.
12. (Amended) A [cancer vaccine] composition according to claim 11 wherein the fragment is of at least 13 contiguous amino acids.
13. (Thrice amended) A [cancer vaccine] composition comprising a nucleic acid molecule which encodes a fragment or derivative as specified in claim 1 [, wherein the vaccine is capable of inducing an immune response in a patient, said immune response being a T cell response].
14. (Twice amended) A [cancer vaccine] composition according to claim 13 having part of [a] the nucleic acid sequence [as] shown [in Fig. 10] below:

ccgctgggag tagctgcgac tcggcggagt cccggcggag cgtccttggt ctaacccggc 60
gcgcc atg acc gtc gcg cgg ccg agc gtg ccc gcg gcg ctg ccc ctc ctc 110
ggg gag ctg ccc cgg ctg ctg ctg ctg gtg ctg ttg tgc ctg ccg gcc 158
gtg ttg ggt gac tgt ggc ctt ccc cca gat gta cct aat gcc cag cca 206
gct ttg gaa ggc cgt aca agt ttt ccc gag gat act gta ata acg tac 254
aaa tgt gaa gaa agc ttt gtg aaa att cct ggc gag aag gac tca gtg 302
atc tgc ctt aag ggc agt caa tgg tca gat att gaa gag ttc tgc aat 350
cgt agc tgc gag gtg cca aca agg cta aat tct gca tcc ctc aaa cag 398
cct tat atc act cag aat tat ttt cca gtc ggt act gtt gtg gaa tat 446
gag tgc cgt cca ggt tac aga aga gaa cct tct cta tca cca aaa cta 494
act tgc ctt cag aat tta aaa tgg tcc aca gca gtc gaa ttt tgt aaa 542
aag aaa tca tgc cct aat ccg gga gaa ata cga aat ggt cag att gat 590
gta cca ggt ggc ata tta ttt ggt gca acc atc tcc ttc tca tgt aac 638
aca ggg tac aaa tta ttt ggc tcg act tct agt ttt tgt ctt att tca 686
ggc agc tct gtc cag tgg agt gac ccg ttg cca gag tgc aga gaa att 734
tat tgt cca gca cca cca caa att gac aat gga ata att caa ggg gaa 782
cgt gac cat tat gga tat aga cag tct gta acg tat gca tgt aat aaa 830
gga ttc acc atg att gga gag cac tct att tat tgt act gtg aat aat 878
gat gaa gga gag tgg agt ggc cca cca cct gaa tgc aga gga aaa tct 926
cta act tcc aag gtc cca cca aca gtt cag aaa cct acc aca gta aat 974
gtt cca act aca gaa gtc tca cca act tct cag aaa acc acc aca aaa 1022
acc acc aca cca aat gct caa gca aca cgg agt aca cct gtt tcc agg 1070
aca acc aag cat ttt cat gaa aca acc cca aat aaa gga agt gga acc 1118
act tca ggt act acc cgt ctt cta tct ggg cac acg tgt ttc acg ttg 1166
aca ggt ttg ctt ggg acg cta gta acc atg ggc ttg ctg act tag 1211
ccaaagaaga gttaagaaga aaatacacac aagtatacag actgttccta gtttcttaga 1271
cttatctgca tattggataa aataaatgca attgtgctct tcatttagga tgctttcatt 1331
gtctttaaga tgtgttagga atgtcaacag agcaaggaga aaaaaggcag tcttggaaac 1391
acattcttag cacacctaca cctcttgaaa atagaacaac ttgcagaatt gagagtgatt 1451
cctttcctaa aagtgtaga aagcatagag atttggtcgt atttagaatg ggaacacgag 1511
gaaaagagaa ggaagtgat tttttccac aagatctgta atgttatttc cacttataaa 1571
ggaataaaaa aatgaaaaac attatttggg tatcaaaaagc aaataaaaaac ccaattcagt 1631
ctcttctaag caaaattgct aaagagagat gaaccacatt ataaagtaat ctttggctgt 1691

aaggcatttt catcttttct tcgggttggc aaaatatattt aaaggtaaaa catgctggtg 1751
aaccaggggt gttgatggtg ataagggagg aatatagaat gaaagactga atcttccttt 1811
gttgacacaaa tagagtttgg aaaaagcctg tgaaaggtgt cttctttgac ttaatgtctt 1871
taaaagtatc cagagatact acaatattaa cataagaaaa gattatatat tattttctgaa 1931
tcgagatgtc catagtcaaa tttgtaaatc ttattctttt gtaatattta tttatattta 1991
tttatgacag tgaacattct gattttacat gtaaaacaag aaaagttgaa gaagatatgt 2051
gaagaaaaat gtatttttcc taaatagaaa taaatgatcc cattttttgg t 2102

or [Fig. 11] the nucleic acid sequence shown below:

tttaaacggg ccctctagac tcgagcggcc gctgcccatc ttgtcgtcgt cgtccttgta 60
gtcgtgcatag tggtggtggt ggtggtggtt aaccatggtg gcgggccgcc actgtgctgag 120
atatctgcag aattcgatgg gcgtagctgc gactcggcgg agtcccggcg gcgcgtcctt 180
gttctaaccg ggcgcgcc atg acc gtc gcg cgg ccg agc gtg ccc gcg gcg 231
ctg ccc ctc ctc ggg gag ctg ccc cgg ctg ctg ctg ctg gtg ctg ttg 279
tgc ctg ccg gcc gtg tgg ggt gac tgt ggc ctt ccc cca gat gta cct 327
aat gcc cag cca gct ttg gaa ggc cgt aca agt ttt ccc gag gat act 375
gta ata acg tac aaa tgt gaa gaa agc ttt gtg aaa att cct ggc gag 423
aaq gac tca gtg atc tgc ctt aaq ggc agt caa tgg tca gat att gaa 471
gag ttc tgc aat cgt agc tgc gag gtg cca aca agg cta aat tct gca 519
tcc ctc aaa cag cct tat atc act cag aat tat ttt cca gtc ggt act 567
gtt gtg gaa tat gag tgc cgt cca ggt tac aga aga gaa cct tct cta 615
tca cca aaa cta act tgc ctt cag aat tta aaa tgg tcc aca gca gtc 663
gaa ttt tgt aaa aaq aaa tca tgc cct aat ccg gga gaa ata cga aat 711
ggt cag att gat gta cca ggt ggc ata tta ttt ggt gca acc atc tcc 759
ttc tca tgt aac aca ggg tac aaa tta ttt ggc tcg act tct agt ttt 807
tgt ctt att tca ggc agc tct gtc cag tgg agt gac ccg ttg cca gag 855
tgc aga gaa att tat tgt cca gca cca cca caa att gac aat gga ata 903
att caa ggg gaa cgt gac cat tat gga tat aga cag tct gta acg tat 951
gca tgt aat aaa gga ttc acc atg att gga gag cac tct att tat tgt 999
act gtg aat aat gat gaa gga gag tgg agt ggc cca cca cct gaa tgc 1047
aga gga aaa tct cta act tcc aaq gtc cca cca aca gtt cag aaa cct 1095

acc aca gta aat gtt cca act aca gaa gtc tca cca act tct cag aaa 1143
acc acc aca aaa acc acc aca cca aat gct caa gca aca cgg agt aca 1191
cct gtt tcc agg aca acc aag cat ttt cat gaa aca acc cca aat aaa 1239
gga agt gga acc act tca ggt act acc cgt ctt cta tct ggg cac acg 1287
tgt ttc acg ttg aca ggt ttg ctt ggg acg cta gta acc atg ggc ttg 1335
ctg act tag ccaaagaaga gttaagaaga aaatacacac aagtatacag 1384
actgttccta gtttcttaga cttatctgca tattggataa aataaatgca attgtgctct 1444
tcatttagga tgctttcatt gtctttaaga tgtgttagga atgtcaaca 1493

19. (Amended) A method of treating a patient having cancer, the method comprising administering to the patient a therapeutically effective amount of a [cancer vaccine] composition as defined in claim 1.
34. (Amended) A [cancer vaccine] composition according to claim 1, wherein said T cell epitope is a T cell epitope of said polypeptide of the CD55 family.